K123843

JUN 5 2013

STROHLMEDICAL

510(k) Summary

Prepared By:	Strohl Medical Technologies, Inc. 126 Prospect Street Norwell, MA 02061
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Contact Person:	Heather Strohl
Date Summary prepared:	October 15, 2012
Name of the Device:	NeuroEPG System
Common Name:	Evoked Response System, Nerve Stimulator/Monitor
Classification Name:	Electrical Evoked Response Stimulator (per CFR882.1870) Auditory Evoked Response Stimulator (per CFR 882.1900)
Patient Population:	18 years of age and older
Environment of Use:	Hospital, clinic, EEG/EP technologist's, surgeon's, or physician's office, operating room
Contraindications:	None
Predicate Device(s):	Intelligent Hearing System *SmartEP* (K070608)

Device Description:
The NeuroEPG System is an evoked response testing and diagnostic device that is capable of eliciting, acquiring, and measuring auditory and somatosensory evoked potentials.

The NeuroEPG System is intended to objectively record evoked responses from patients 18 years of age and older, upon the presentation of sensory stimuli. The product is indicated for use as a

diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory) and in surgical procedures for intraoperative monitoring.

Indications for Use:

The NeuroEPG System is an evoked response testing and diagnostic device that is capable of eliciting, acquiring and measuring auditory and somatosensory evoked potentials.

The intended use of the NeuroEPG System is to objectively record evoked responses from patients 18 years of age and older, upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory) and in surgical procedures for intraoperative monitoring.

The NeuroEPG System is intended to be used by trained personnel in a hospital, clinic, EEG/EP technologist's, surgeon's, or physician's office, operating room, or other appropriate setting.

The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery ear bud), and the patient's head and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for somatosensory evoked potential (SEP) testing are the patient's upper/lower limbs (with the contact object being skin-surface electrodes) and the patient's head and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

Table of Comparison and Differences vs. Predicates

The modifications described in this table are only concerned with the Auditory Evoked Potentials (AEP) and the Somatosensory Evoked Potential (SEP) testing aspects of the predicate device.

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Parameter	**Predicate Device** ***SmartEP (K070608)***	***The NeuroEPG System***
Intended Use	SEP: Stimulate, record, and process somatosensory evoked potentials AEP: Stimulate, record, and process auditory evoked potentials	Same
Indications for Use	The recording and analysis of physiological data necessary for the diagnosis of somatosensory and auditory related disorders.	Same
Target Population	All Ages	18 years and older
Design	External box housing circuitry connected to CPU via a USB connection	Same
Sterility	Non-sterile	Same
Anatomical Sites	SEP: Upper/lower limbs and Head AEP: Head	Same
Energy Delivery	SEP: Stimulation of upper or lower limbs with surface electrical signals AEP: Stimulation of ears with auditory stimulus	Same
Where Used	Clinical Setting	Same
Safety	Conforms to IEC 60601-1	Same

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Parameter	**Predicate Device** *SmartEP (K070608)*	***The NeuroEPG System***
Patient Isolation	Type BF (IEC 60601-1) Fiber Optic Signal Link	Same
Somatosensory Stimuli		
Types	Constant Current or Voltage	Constant Current
Mode	User selectable: Single, Dual, or Stimulus Train	Same
Shape	Mono or Biphasic pulses	Same
Repetition Rate	0.1 - 100 Hz	Same
Phase/Polarity	Positive or Negative	Same
Duration /Pulse Width	10 - 1000 µs	Same
Stimulus Intensity Levels	Current: 0 - 100 mA Voltage: 0 - 400V (Continuous adjustable level with user selectable maximum range into a 4000 Ohms load)	Current: 0 – 25 mA Voltage: 0 – 50V (Continuous adjustable level with user selectable maximum range into a 2000 Ohms load)
Auditory Stimuli		
Types	Clicks, Pure Tones, Multifrequency Stimuli	Same
Duration	25-5000 µs	Same
Envelopes	Linear, Blackman, Gaussian, Hanning, Rectangular, Triangular, Trapezoidal, Exact Blackman, Cosine, Cosine Squared, Cosine Cubed	Same
Intensity	0-125 dB SPL	Same

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Parameter	**Predicate Device** ***SmartEP (K070608)***	***The NeuroEPG System***
Repetition Rate	1-100 Hz	Same
Test Frequencies	500-16,000 Hz	Same
Presentation	Monaural or Binaural	Same
Masking	White Noise Programmable	Same
Transducers	Insert Earphones, Bone Vibrator, Headphones, Sound Field, Ear Probe	Ear buds only
Measurement Parameters		
Analysis Window	Variable (up to 2.5 msec)	Same
Artifact Rejection Threshold	User Selectable	25μV
Measured Values	Response Level (μV) Noise Level (μV) Signal to Noise Ratio (dB) Response Latency (msec) Frequency (Hz)	Same plus left versus right comparison
Computer Requirements		
Computer Type	Personal Computer	Same
Operating System	Microsoft Windows 2000 or XP	Same
Interface Connection	USB (Universal Serial Bus)	Same

Technological Characteristics:

The NeuroEPG System hardware is based on modifications to the predicate device. Modifications were made by Intelligent Hearing Systems, the OEM of the predicate.

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The NeuroEPG hardware is very similar in electronics design to the predicate device hardware, except that the electronics hardware has been repackaged into a single, smaller, stand-alone unit. Unlike the predicate devices, there is no separate pre-amplifier unit connected to the patient in the NeuroEPG System. Instead, all of the pre-amplifier electronics have been embedded inside of the NeuroEPG Data Acquisition Unit. The same patient isolation methods are used.

The software changes within the data acquisition unit are minor and do not alter the safety and effectiveness of the device in any way. The software incorporates a reduced range of testing and analysis parameters so a broader set of personnel can perform an evoked response test. Strohl Medical has additional software that operates on the data from the data acquisition unit.

Safety and Effectiveness:
The NeuroEPG System utilizes the same design principles, circuit designs, and operating principles as are used in the predicate device.

The NeuroEPG System meets the requirements of IEC 60601-1 and IEC 60601-1-2 for electrical safety and electromagnetic compatibility respectively. It also meets the requirement of IEC 60601-2-40 for electromyographs and evoked response equipment. The disposable (PIK) meets the requirements of ANSI/AAMI EC12 for Disposable ECG Electrodes and ANSI/AAMI EC53 for ECG Cables and Leadwires as well as clause 56.3c of IEC 60601-1 (1998) [21CFR898].

Substantial Equivalence
The stimulation and response mechanism are identical to the predicate. The fundamental scientific technology of the NeuroEPG System is identical to the predicate.
The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications – Equivalent to the predicate

Technology – The technology is identical

Operating specifications – Equivalent

Materials – The patient contact materials are identical to those in other legally marketed devices.

Environment of Use – Identical

Patient Population – Restricted to adults

Differences:
There are no significant differences between the proposed device and the predicate device.

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Comparative Performance and Specifications
The NeuroEPG System is substantially equivalent to the SmartEP device marketed by Intelligent Hearing systems with FDA 510(k) clearance number K070608.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 5, 2013

Strohl Medical Technologies
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K123843
Trade/Device Name: NeuroEPG System
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, GWJ, GXY
Dated: May 14, 2013
Received: May 15, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123843

Device Name: NeuroEPG System

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Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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